## B. ADMINISTRATIVE INFORMATION

MAR 2 0 2013

### B.1 510(k) Summary of Safety and Effectiveness

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| **Date of summary:** | 14 January 2013 |
| **Submitter's name:** | Mirada Medical Ltd |
| **Submitter's address:** | Oxford Centre for Innovation, New Road, Oxford. Oxfordshire, OX1 1BY United Kingdom |
| **Submitter's contact:** | Gwilym Owen |
| **Telephone number:** | +44 (0)1865 261417 |
| **Device Proprietary Name:** | RTx |
| **Device Common Name(s):** | RTx, RT Server, RTx Server, Workflow Box |
| **Classification Name:** | Class II: Picture Archiving and Communications System (892.2050) Product Code: LLZ |

RTx is Substantially Equivalent to the following Legally Marketed devices:

**Predicate Devices**

| 510(k) Number | Trade Name | Manufacturer |
|---|---|---|
| K102687 | Mirada RT | Mirada Medical Ltd |
| K091373 | Syngo TrueD Software | Siemens Medical Solutions USA, Inc. |
| K093982 | XELERIS 3 PROCESSING AND REVIEW WORKSTATION | GE Healthcare |
| K081076 | VelocityAIS | Velocity Medical Solutions, LLC |

#### B.1.1 Intended Use

RTx is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, radiation oncologists, dosimetrists and physicists.

RTx is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include static and gated CT, PET, MR, SPECT and planar NM. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

RTx allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

RTx provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

RTx supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform, store and export such objects including regions of interest structures and dose volumes to radiation therapy planning systems. RTx allows the user to transform regions of interest associated with a particular imaging dataset to another, supporting atlas-based contouring and rapid re-contouring of the same patient.

### B.1.2 Device Description

RTx is a software application for displaying and visualizing 2D & 3D multi-modal medical image data such as static and gated CT, PET, MR, SPECT and planar NM. RTx runs on a workstation with color monitor(s), keyboard, mouse and optional CD-RW or may be deployed on a server. RTx is designed to enable rendering, reviewing, storing, printing and distribution of DICOM 3.0 compliant datasets and reports within the system and/or across computer networks.

RTx enables automatic and manual registration of combinations of anatomical and functional images that can be displayed with fused and non-fused displays to facilitate the comparison of image data by the user.

RTx provides a number of tools such as rulers and semi-automated and manual regions of interest for the assessment of regions of an image to support a clinical workflow. RTx supports the loading and saving of DICOM RT objects and allows the user to define, import, display, transform and store and export such objects including regions of interest structures and dose volumes to radiation therapy planning systems.

### B.1.3 Testing

RTx is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission. The results of performance, functional and algorithmic testing demonstrate that RTx meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate devices.

Verification and Validation for RTx has been carried out in compliance with the requirements of ISO 13485:2003, CFR 21 Part 820 and in adherence to the DICOM standard.

In conclusion, performance testing demonstrates that RTx is substantially equivalent to, and performs at least as safely and effectively as the listed predicate devices. RTx meets requirements for safety and effectiveness and does not introduce any new potential safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Mirada Medical Ltd LLC.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130393
Trade/Device Name: RTx
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 12, 2013
Received: March 13, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K130393 Device Name: RTx

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130393